

# **CENTER FOR DRUG EVALUATION AND RESEARCH**

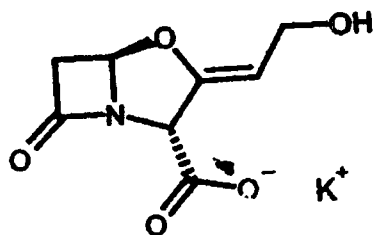
***APPLICATION NUMBER:***

**50-720/S-017**

**CHEMISTRY REVIEW(S)**

**NDA Supplement Review**  
**Chemistry, Manufacturing, and Controls**  
**Division of Anti-Infective Drug Products (HFD-520)**

1. **NDA NUMBER/SUPPLEMENT:** 50-720/SCS-017
2. **REVIEW:** # 1
3. **REVIEW DATE(s):** 9/27/02; **LETTER DATE:** 6/14/02
4. **STAMP DATE:** 6/17/02; **DUE DATE:** 10/17/02
5. **SUPPLEMENT PROVIDES FOR:** Change assay acceptance limits for clavulanate potassium calculated on an \_\_\_\_\_ basis from \_\_\_\_\_
6. **PREVIOUS DOCUMENTS:** None
7. **SUBMISSION(S) BEING REVIEWED:** Original Supplement
8. **NAME AND ADDRESS OF APPLICANT**  
GlaxoSmithKline  
1250 South Collegeville Road  
P. O. Box 5089  
Collegeville, PA 19426-0989  
S. LoCastro (610)-917-6457
9. **DRUG PRODUCT NAME:**  
**Proprietary Name :** Augmentin® Tablets  
**Nonproprietary Name:** Amoxicillin/clavulanate potassium Tablets
10. **PHARMACOLOGICAL CATEGORY:** Anti-infective
11. **DOSAGE FORM:** Tablet
12. **STRENGTH/POTENCY:** 875 mg
13. **ROUTE OF ADMINISTRATION:** Oral
14. **Rx/OTC DISPENSED:** ☒ Rx ☐ OTC
15. **CHEMICAL NAME, CHEMICAL STRUCTURE, MOLECULAR FORMULA, and MOLECULAR WEIGHT:** Since the supplemental application is for the specifications of clavulanate potassium, item 15 listing is only for this compound.  
Clavulanate Potassium:  $C_8H_8KNO_5$   
Potassium(Z)-(2R,5R)-3-(2-hydroxyethylenedene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate.  
Mol. Weight for Clavulanate potassium: 237.25  
CAS Registry Number: [61177-45-5]



**16. RELATED/SUPPORTING DOCUMENTS:** Bundled with the following NDA:50-564/S045, 50-575/S034, 50-597/S041, 50-590/S047, 50-658/S015, 50-725/S020, 50-726/S016, 50-755/S005, and ANDA:62-691.

**17. COMMENTS:** # 7048 is a Type II DMF referenced for the proposed change of this supplement as an Amendment. The supplement holder is GlaxoSmithKline and the Amendment date is June 13, 2002. The date of DMF Amendment review is 10/9/02 and the proposed change in the Amendment is adequate. See lead review for NDA 50-590/SCS-047.

**18. CONCLUSIONS AND RECOMMENDATIONS:** Recommend an approval letter be issued for this supplement.

CC:

HFD-520/Samanta

HFD-520/ChemTL/Katague

HFD-830/Dunn

HFD-520/Yu

HFD-80/S.Lange

**ASSESSMENT:**

**Laboratory Controls (in-process and finished dosage forms) : Adequate**

This application is bundled with the following NDA: 50-564/S045, 50-575/S034, 50-597/S041, 50-590/S047, 50-658/S015, 50-725/S020, 50-726/S016, 50-755/S005, and ANDA:62-691. See lead review for NDA 50-590/SCS-047.

**APPEARS THIS WAY  
ON ORIGINAL**